REMARKS

Reconsideration of this application is respectfully requested. Claims 22-48 are pending and at issue.

Claims 22-48 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner contends that the claimed method is not enabled as the specification "does not specify which of the types [of preparations of Mycobacterium w] was actually utilized nor how much of the composition was administered" (page 6 of the March 9, 2007 Office Action). The Examiner has further stated that "while the specification does recite 8 different preparations, the specification does not indicate which preparation was actually utilized" (page 2 of the October 28, 2008 Office Action). Applicants respectfully traverse the rejection.

Contrary to the Examiner's assertion, the specification enables the presently claimed methods of treating obstructive lung disease by administering a pharmaceutical composition comprising an effective amount of mycobacterium w or a constituent of mycobacterium w. The specification exemplifies how to make the pharmaceutical composition, how much of the pharmaceutical administration can be administered as well as suitable routes of administration. Example 1 in the specification describes 10 formulations (labeled A-J). The active ingredient in these compositions is heat killed mycobacterium w or an extract of mycobacterium w. Example 2 describes various methods for obtaining the active ingredient for these formulations. Example 3 explicitly states that the fraction of mycobacterium w that elutes at 11 minutes by HPLC analysis with a specific column is suitable for the pharmaceutical composition of the present invention. Examples 4-8 illustrate the efficacy of these compositions, and teach how to use them. For instance, example 4 states that the pharmaceutical composition can be intradermally administered. *See* page 13, line 8, of the original specification. Example 6 describes an experiment where 0.1 ml of the pharmaceutical composition of the present invention was administered once a week and found to improve lung function.

The Examiner has previously questioned which compositions were administered to patients in the working examples described in the specification. Applicants have previously

submitted declarations pursuant to 37 C.F.R. §1.132 by Drs. Bakulesh Khamar and James P. Lamberti addressing this issue. The October 28, 2008 Office Action does not address these declarations or the data contained in them. "Evidence traversing rejections, when timely presented, must be considered by the examiner whenever present." MPEP 716.01(B). Accordingly, applicants respectfully request that the Examiner acknowledge and comment upon all entered declarations in the event that this rejection is maintained.

As indicated in Dr. Khamar's declaration, the composition of Example 1A in the specification was used in the experiments described in Examples 4-6. The declaration further states that the compositions of Examples 1A and 1D were used in the experiments described in Examples 7 and 8.

Dr. Lamberti's declaration establishes that a skilled artisan would have been able to practice the invention without undue experimentation. Paragraphs 5-10 of his declaration explain in detail how a skilled artisan would interpret the teachings of the instant specification. Dr. Lamberti concludes that "[o]ne of ordinary skill in the art of pulmonary medicine would understand (1) that the appropriate therapeutic dosage is typically 0.1 ml of Mycobacterium w, but could also be twice this dosage for patients with a higher degree of respiratory impairment, (2) the dosage may include whole cells, sonicated cells, or extracted cell fractions, (3) the composition could be administered intradermally or by nebulizer approximately once per week, and (4) treatment could be continued from four weeks to three months, or longer or shorter depending on the response exhibited by the patient to the treatment" (paragraph 11 of Dr. Lamberti's deposition).

Applicants wish to further point out that the composition described in Example 1(A) of the present specification is approved for human use in India and marketed in India by Cadila Pharmaceutical Ltd. under the trademark IMMUVAC. The studies performed with this product establish its efficacy. For instance, Example 4 of the present specification describes a study in which patients were given 0.2 ml of this composition initially once per week intradermally followed by a dosage of 0.1 ml per week. *See* paragraph 4 of Dr. Khamar's December 19, 2007 declaration. In Example 5, the patients were given IMMUVAC® as disclosed in example 1 A containin g

Mycobacterium w containing pharmaceutical composition at a dosage of 0.1 ml administered intradermally once per fortnight. *Id.* In Example 6, IMMUVAC® as disclosed in example 1 A containing Mycobacterium w pharmaceutical composition was administered via a nebuliser. *Id.* In Example 7, the patients were given a IMMUVAC® as disclosed in example 1 A containing Mycobacterium w pharmaceutical composition at a dosage of 0.1 ml either through intra-dermal or inhalation route at a frequency of one dosage every fortnight. *Id.* In Example 8, the patients were given a Mycobacterium w containing pharmaceutical composition at a dosage of 0.1 ml. *Id.*

Applicants submit that the presently claimed methods are sufficiently described in the specification in such a way as to enable one skilled in the art to make and use the claimed invention and respectfully request withdrawal of the rejection. Should the Examiner feel that the declarations of Drs. Khamar and Lamberti are somehow deficient, the Examiner is invited to "specifically explain why the evidence is insufficient," as mandated by MPEP 716.01.

In view of the above remarks, applicants believe the pending application is in condition for allowance.

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Respectfully submitted,

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